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Attorney Docket No. 19705-010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Thomas T. Andersen *et al.*		
APPLICATION NO:	09/872,623	EXAMINER:	Sheela Jitendra Huff
FILING DATE:	June 2, 2001	ART UNIT:	1642
FOR:	*ALPHA-FETOPROTEIN PEPTIDES AND USES THEREOF*		

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. THOMAS ANDERSEN UNDER 37 C.F.R. §1.132

I, THOMAS ANDERSEN, of 15 Catalpa Drive, Albany, NY 12209, declare and state that:

1. I am a co-inventor, together with James Bennett, Herbert Jacobson, and Fassil Mesfin, in the above-referenced patent application.

2. I received a Ph.D. from the University of Kansas in 1978, and received post-doctoral training at Duke University.

3. I am currently employed by Albany Medical College ("AMC") as an Assistant Dean and teaching professor. The Assignee to this invention, CLF Medical Technology Acceleration Program, Inc., is the licensing arm for AMC. A principal aspect of my role at AMC has been studying and elucidating alpha-fetoprotein ("AFP") because this fetal protein, when incubated with estrogen, acquires the ability to prevent the growth of estrogen-dependent breast cancers. This protein is the subject matter of the present invention.

4. I have reviewed, and understand, the above-referenced application, and its updated claims as amended in the Response to be filed concurrently herewith. I have also reviewed the Office Action dated August 25, 2003. I understand that claims 1-3 and 5 stand rejected under 35 U.S.C. § 102(a) as anticipated by Mesfin *et al.* (2001), a paper written by the joint

inventors of the instant application (hereinafter "Mesfin"). Mesfin discloses sequences within the scope of claims 1-3 and 5, namely EMTOVNOG and EMTOVNOGQ.

5. I now submit, on behalf of all the inventors, evidence indicating conception and reduction to practice of the peptides disclosed by Mesfin, prior to the March 2001 publication date of Mesfin. This evidence regarding EMTOVNOG (SEQ ID NO:4) and EMTOVNOGQ (SEQ ID NO:5) is attached hereto as Exhibit A.

6. Presented in Exhibit A are six (6) pages which are true copies from Applicants' notebooks leading to the invention of the instant application. These pages show the synthesis and bioassay of SEQ ID NO:5 (EMTOVNOGQ) on June 3-4, 2000, and June 8-9, 2000, respectively. As denoted in our lab notebooks, the name of the peptide is 9merHyPro. This is shorthand for a peptide of 9 amino acids wherein the proline (P) residues were both substituted by Hydroxyproline (O). Although the sequence on the first sheet indicates Pro in positions 4 and 7, the synthesizer computer uses the Pro code by default. The synthesizer was not re-programmed to print HyPro in place of Pro.

7. Page 2 of Exhibit A is dated June 8, 2000 and represents the concentrations of the peptide to be tested in the Uterine Growth Assay as disclosed in the instant application. The remaining pages of Exhibit A, dated June 9, 2000, detail the findings of the assay.

8. Thus, peptides disclosed by Mesfin (EMTOVNOG (SEQ ID NO:4) and EMTOVNOGQ (SEQ ID NO:5)) are documented to be in our possession well before the March 2001 publication date of Mesfin. Accordingly, Mesfin cannot anticipate claims 1-3 and claim 5, and the rejection should be withdrawn.

9. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

Thomas T. Andersen, Ph.D.

Signed at Albany, NY

this 24 day of November, 2003

TRA 1855806v1

Notebook Name:	9merHyPro
Protocol Name:	\Template
Chemistry Name:	\OH Derivatives
Final Cycle:	Fmoc off
Start time:	06/03/00, 02:09:11 PM
Finish time:	06/04/00, 01:38:41 AM
Status:	Complete
Instrument name:	Pioneer
Synthesis Position:	1
Sequence Name:	9merHyPro
Sequence:	Glu - Met - Thr - Pro - Val - Asn - Pro - Gly - Gln -
Sequence length:	9
First AA Support:	Off

Uterine Bioassay
6 - 8 - 00

I	Sal		Sal
II	Sal		E_2
III	Fresh 9 mer oN·Hol made 6-4-00 CY-PL 6-6-00	1 mg	E_2
IV	"	10 mg	E_2
V	"	100 mg	E_2
VI	"	1 ug	E_2
VII	"	10 ug	E_2
VIII	"	100 ug	E_2

weigh out 700 ug dissolve in 3.5 ml PBS 200 ug/ml in 0.1

0.3	+ 2.7	20 ug/ml
"	"	2 ug/ml
"	"	200 ng/ml
"	"	20 ng/ml
"	"	2 ng/ml

Neonatal Autopsy

Date 06-9-00

Treatment:	Birth Date	Age in Days	Body wt. (grams)	Uterine wt. (mg)	UW/BW ratio ($\times 10^{-3}$)	$\bar{X} \pm SD$
I sal. sal.						
1			7.94	4.9	0.61_7	$0.83_8 \pm 0.16_0$
2			8.34	8.4 JB	1.00_7	
3			8.30	6.8 JB	0.81_9	
4			8.12	8.0	0.98_5	
5			7.35	5.6 JB	0.76_2	
II sal E_2						
1			9.96	15.0 JB	1.67_4	$1.61_2 \pm 0.16_0$
2			7.61	12.2	1.60_2	
3			8.25	13.6 JB	1.64_8	$S\bar{x}_{III} = 0.77_4$
4			8.35	14.9 JB	1.78_4	
5			7.69	10.4	1.35_2	

$1.41_2 / 0.83_8$

Neonatal Autopsy

Date 06-9-00

Treatment:		Birth Date	Age in Days	Body wt (grams)	Uterine wt. (mg)	UW/BW ratio (x10⁻³)	$\bar{X} \pm SD$
VII Fresh gavage E_2							
Hy-pro	1			9.14	9.0 JB	0.98_4	$1.61_6 \pm 0.41_6$
~~10 mg~~ Yug	2			7.66	11.3	1.47_5	
	3			8.69	14.5 JB	1.66_4	—
	4			7.40	15.4 JB	2.08_1	
	5			8.67	16-0	1.84_6	
VIII Fresh gavage E_2							
Hy-pro	1			8.60	13.5 JB	1.57_0	$1.48_5 \pm 0.14_4$
~~100 mg~~	2			8.90	10-9	1.22_5	
10 mg	3			7.35	11.5 JB	1.56_4	0.12_4 15%
	4			8.38	13.1 JB	1.56_3	
	5			7.44	11.3	1.51_9	

1.61₂ / 0.83₉

Neonatal Autopsy

Date 06-8-00

Treatment:		Birth Date	Age in Days	Body Wt. (grams)	Uterine Wt. (mg)	UW/BW ratio (x10⁻³)	x̄ ± SD
VI Fresh Sweet E2							
Hy-pro	1			8.76	12.6 JB	1.43₈	1.48₄ ± 0.08₅
100 ng	2			8.68	13.9 JB	1.60₁	
	3			7.80	11.8	1.51₃	0.13₁ 16%
	4			7.98	11.8 JB	1.47₉	
	5			8.16	11.2 JB	1.37₂	
VI Fresh Sweet E2							
Hy-pro	1			8.68	12.2	1.40₆	1.40₄ ± 0.13₂
1 ug	2			7.38	9.8 JB	1.32₈	
	3			7.92	9.8 JB	1.23₇	0.20₃ 24%
	4			8.08	12.8	1.58₄	
	5			8.58	12.8 JB	1.49₂	

1.61₂/0.83₄

Neonatal Autopsy

Date 06-9-00

Treatment:		Birth Date	Age in Days	Body wt. (grams)	Uterine wt. (mg)	UW/BW ratio (x 10^{-3})	$\bar{X} \pm SD$
VII Fresh Syrup E_2							
Hy-pro	1			7.76	11.1 JB	1.43_0	$1.44_4 \pm 0.15_5$
10 µg	2			7.93	10.1	1.27_4	
	3			9.01	14.5 JB	1.60_9	0.17_1 20%
	4			8.72	13.9	1.59_4	
	5			8.23	10.7 JB	1.30_0	
VIII Fresh Syrup E_2							
Hy-pro	1			8.02	14.2 JB	1.77_1	$1.76_2 \pm 0.39_0$
100 µg	2			8.01	10.9	1.36_1	
	3			7.87	14.0 JB	1.77_9	—
	4			8.56	20.4 JB	2.38_3	
	5			8.51	12.9	1.51_5	